

Category

Best Medical Technology

Drug / Device Name

The Jada® System

Compound/ Tech Name

Intrauterine vacuum-induced hemorrhage-control device

Trade Name

The Jada® System

Date of Approval

2020-08-28

Indications

The Jada System is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted.

Therapeutic Categories

Maternal Health/Obstetrics

Background information and need for drug/device

Postpartum hemorrhage (PPH) occurs in up to 10.5% of all births globally, with incidences generally higher in developing nations. The World Health Organization (WHO) estimates that 14 million cases occur globally each year, which in some cases may result in major complications, including blood transfusions or surgical interventions. Despite this, treatment for PPH has lacked significant innovation until recently.

When PPH or abnormal postpartum uterine bleeding occurs, finding the cause of bleeding and initiating treatment without delay is critical. The faster bleeding is controlled, the less likely a woman is to receive a blood transfusion, experience complications, or require more invasive interventions.

While PPH can have multiple causes, the most common is when the uterus is fatigued and doesn't effectively contract following childbirth, leaving blood vessels uncontracted where the placenta separates from the uterine wall. Until the JADA® System became available, there was no device that could help the uterus to contract as it should following childbirth. Standard of care has historically consisted of uterotonic agents (such as Oxytocin), up to 24 hours of uterine compression via a uterine tamponade or packing the uterus with sponges and sterile materials to staunch the bleeding. The last significant development in care before JADA was over 20 years ago with the development of the balloon tamponade, currently the standard-of-care second-line treatment for PPH. JADA has the potential to change the approach to treating PPH.

JADA is made of soft silicone and consists of an intrauterine loop, a cervical seal, and tubing for connection to a regulated vacuum source. When placed inside the uterus and connected to a vacuum source, blood is evacuated through the small pores located in the intrauterine loop. The vacuum created within the uterus causes the physiological contraction of the uterus to provide control and treatment of postpartum bleeding.

History of the development of the drug/device

In 2010, California Polytechnic State University students developed a concept for a medical device that would use a low-level vacuum to induce uterine contractions to stop bleeding after childbirth. This concept was developed into the JADA® System at Alydia Health, a medical device company acquired by Organon in 2021. The second model of JADA was cleared for market in 2021 and is designed to facilitate ease of use by obstetricians or midwives.

In a pivotal clinical trial (the PEARLE study) that took place at 12 leading U.S. hospitals, JADA effectively controlled PPH in 94% of cases with no further intervention needed to control the bleeding. Control of bleeding occurred in a median of 3 minutes, and the median total therapy duration was 3.2 hours. Almost all (98%) investigators involved in found the device easy to use. There was a low rate of adverse events potentially related to the device, with five events rated as “moderate” and none as “severe.” Three of the moderate events were cases of endometritis, vaginal exam, and postpartum hemorrhage.

This February, results from the first large real-world, observational, post-market registry study of JADA (RUBY study) were presented at Society for Maternal-Fetal Medicine’s (SMFM) annual meeting. Investigators reviewed medical records of 800 women treated with JADA in 16 U.S. centers which suggested that JADA effectively controlled bleeding in 92.5% of vaginal deliveries and 83.7% of Cesarean deliveries. A low rate of adverse events were deemed possibly related to the device, where three serious events were deemed possibly device-related, including hemorrhagic shock and endometritis. This study was one of five (selected from 1,000+ accepted abstracts) that SMFM chose to highlight in a stand-alone press release.

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition

The impact of PPH is profound and far-reaching, especially in low- and lower-middle income nations, where health infrastructure is less developed, and treatments like blood transfusions are often not readily available. The potential to equip doctors, midwives, and other caregivers with tools to help control and treat PPH is a massive achievement in public health. Additional work is underway for JADA to be usable in multiple care settings and with practitioners of various skill levels. In working toward this goal, researchers are investigating the specific needs and requirements of practitioners in low-resource settings to determine the optimal solution to help implement JADA.

In addition to addressing an important clinical need, JADA represents the commitment of Organon to funding, refining, and bringing to market real innovations aimed at conditions that affect women, where care has often been allowed to stagnate despite the wide reach and impact of these conditions.

This March, Organon was invited to present at WHO's first-ever Postpartum Haemorrhage Summit in Dubai. This landmark summit brought together researchers, industry, policymakers, funders, intergovernmental organizations, non-governmental organizations, and international organizations in maternal health. WHO's goal is to create momentum and mobilize the international community with

the ambition of accelerating progress and jointly developing a common agenda for research, guidelines, advocacy, and country-level implementation in the maternal health field. Organon was proud to participate in this prestigious meeting and educate WHO about the work Organon is doing in maternal health.

Please provide appropriate references (ie Pubmed links)

Profile of the Jada® System: the vacuum-induced hemorrhage control device for treating abnormal postpartum uterine bleeding and postpartum hemorrhage: <https://pubmed.ncbi.nlm.nih.gov/34355991/>

Intrauterine Vacuum-Induced Hemorrhage-Control Device for Rapid Treatment of Postpartum Hemorrhage: <https://pubmed.ncbi.nlm.nih.gov/32909970/>

A device that could save the lives of thousands of new mothers earned a startup a \$240 million exit. Its 11-year journey to market shows how gender biases are holding back women's health: <https://fortune.com/2022/12/28/alydia-health-jada-system-maternal-deaths-womens-health-gender-bias/?ejf202>